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HCCA 2017 Compliance Institute

21st Century Cures Act

Calls for additional guidance:

- Accessing and sharing PHI for research purposes, including prep to research
- w/ONC, common legal, governance and security barriers that prevent trusted exchange of health info
- w/ONC, improving individual access to health information, including from BAs
- Ability to disclose treatment-related information about persons with mental health disorders, such as with close friends and family

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Long-term Regulatory Agenda

- HITECH provision re: providing individuals harmed by violations of the HIPAA regulations with a percentage of any civil monetary penalties or settlements collected.
- HITECH provisions re: changes to HIPAA Accounting of Disclosure provisions.

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Upcoming Guidance/FAQs

- Privacy and Security for "All of Us" (PMI) research program
- Text messaging
- Social Media
- Use of CEHRT & compliance with HIPAA Security Rule (w/ONC)
- RA/CMP Process
- Update of existing FAQs to account for Omnibus and other recent developments
- Minimum necessary

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Recent Guidance: Ransomware and Cloud Computing

- Ransomware:
  - http://www.hhs.gov/hipaa/for-professionals/security/guidance/index.html
- Cloud Computing:
  - https://www.hhs.gov/hipaa/for-professionals/special-topics/cloud-computing/index.html

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5

Monthly Guidance: Cybersecurity Newsletters

February 2016	Ransomware, "Tech Support" Scam, New BBB Scam Tracker
March 2016	Keeping PHI safe, Malware and Medical Devices
April 2016	New Cyber Threats and Attacks on the Healthcare Sector
May 2016	Is Your Business Associate Prepared for a Security Incident
June 2016	What's in Your Third-Party Application Software
September 2016	Cyber Threat Information Sharing
October 2016	Mining More than Gold (FTP)
November 2016	What Type of Authentication is Right for you?
December 2016	Understanding DoS and DDoS Attacks
January 2017	Audit Controls
February 2017	Reporting and Monitoring Cyber Threats

http://www.hhs.gov/hipaa/for-professionals/security/guidance/index.html

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6

Audit Purpose: Support Improved Compliance

- Identify best practices; uncover risks & vulnerabilities; detect areas for technical assistance; encourage consistent attention to compliance
  - Intended to be non-punitive, but OCR can open up compliance review (for example, if significant concerns are raised during an audit or an entity fails to respond)
- Learn from this next phase in structuring permanent audit program
- Develop tools and guidance for industry self-evaluation and breach prevention

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Audit Program Status

- Desk audits underway
  - ✓ 166 Covered Entities
  - ✓ 43 Business Associates
- Business Associate selection pool largely drawn from over 20,000 entities identified by audited CEs
- On-site audits of both CEs and BAs in 2017, after completion of the desk audit process, to evaluate against a comprehensive selection of controls in protocols
- A desk audit subject may be subject to on-site audit
- OCR beginning distribution of draft findings

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Desk Audit Reporting: Process

After review of submitted documentation:

- Draft findings shared with the entity
- Entity may respond in writing

Final audit reports will:

- Describe how the audit was conducted
- Present any findings, and
- Contain any written entity responses to the draft

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Covered Entity Desk Audit Controls

Privacy Rule Controls	Notice of Privacy Practices & Content Requirements [§164.520(a)(1) & (b)(1)]
	Provision of Notice – Electronic Notice [§164.520(c)(3)]
	Right to Access [§164.524(a)(1), (b)(1), (b)(2), (c)(2), (c)(3), (c)(4), (d)(1), (d)(3)]
Breach Notification Rule Controls	Timeliness of Notification [§164.404(b)]
	Content of Notification [§164.404(c)(1)]
Security Rule Controls	Security Management Process -- Risk Analysis [§164.308(a)(1)(ii)(A)]
	Security Management Process -- Risk Management [§164.308(a)(1)(ii)(B)]

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Business Associate Desk Audit Controls

Breach Notification Rule Controls	Notification by a Business Associate [§164.410, with reference to Content of Notification §164.404(c)(1)]
Security Rule Controls	Security Management Process -- Risk Analysis [§164.308(a)(1)(ii)(A)]
	Security Management Process -- Risk Management [§164.308(a)(1)(ii)(B)]

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Audit Guidance

Selected protocol elements with associated document submission requests and related Q&As	**Slides from audited entity webinar held July 13, 2016**	**Comprehensive question and answer listing**

OCR Website:
http://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/audit/index.html

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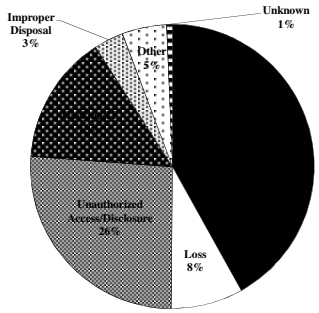
500+ Breach Reports as of 2/28/2017



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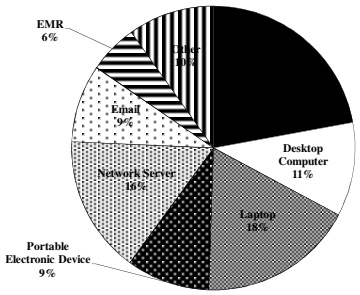

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Complaints Received and Cases Resolved

- Over 150,507 complaints received to date
- Over 24,879 cases resolved with corrective action and/or technical assistance
- Expect to receive 17,000 complaints this year

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Enforcement Guidance: How OCR Closes Cases

- https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/data/index.html
- Cases that OCR closes fall into five categories:
  - Resolved after intake & review (no investigation)
  - Technical Assistance (no investigation)
  - No Violation (investigated)
  - Corrective Action Obtained (investigated; includes Resolution Agreements)
- OCR may decide not to investigate a case further if :
  - The case is referred to the Department of Justice for prosecution.
  - The case involved a natural disaster.
  - The case was pursued, prosecuted, and resolved by state authorities.
  - The covered entity or business associate has taken steps to comply with the HIPAA Rules and OCR determines enforcement resources are better/more effectively deployed in other cases.

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Recent Enforcement Actions

- https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/index.html
- 2/16/2017: HIPAA settlement shines light on the importance of audit controls
- 2/1/2017: Lack of timely action risks security and costs money
- 1/18/2017: HIPAA settlement demonstrates importance of implementing safeguards for ePHI

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Continuing Enforcement Issue: Affirmative Disclosures Not Permitted

The HIPAA Privacy Rule provides that Covered Entities or Business Associates may not use or disclose PHI except as permitted or required. See 45 C.F.R. § 164.502(a). Examples of Potential Violations:

- Covered Entity permits news media to film individuals in its facility prior to obtaining their authorization.
- Covered Entity publishes PHI on its website or on social media without an authorization from the individual(s).
- Covered Entity confirms that an individual is a patient and provides other PHI to reporter(s) without authorization from the individual.
- Covered Entity faxes PHI to an individual's employer without authorization from the individual.

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Continuing Enforcement Issue: Lack of Business Associate Agreements

HIPAA generally requires that covered entities and business associates enter into agreements with their business associates to ensure that the business associates will appropriately safeguard protected health information. See 45 C.F.R. § 164.308(b).
Examples of Potential Business Associates:

- A collections agency providing debt collection services to a health care provider which involves access to protected health information.
- An independent medical transcriptionist that provides transcription services to a physician.
- A subcontractor providing remote backup services of PHI data for an IT contractor-business associate of a health care provider.

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Continuing Enforcement Issue: Incomplete or Inaccurate Risk Analysis

- Conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information held by the [organization]. See 45 C.F.R. § 164.308(a)(1)(ii)(A).
- Organizations frequently underestimate the proliferation of ePHI within their environments. When conducting a risk analysis, an organization must identify all of the ePHI created, maintained, received or transmitted by the organization.
- Examples: Applications like EHR, billing systems; documents and spreadsheets; database systems and web servers; fax servers, backup servers; etc.); Cloud based servers; Medical Devices Messaging Apps (email, texting, ftp); Media

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Risk Analysis Guidance

- http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/rafinalguidance.html
- http://scap.nist.gov/hipaa/
- http://www.healthit.gov/providers-professionals/security-risk-assessment

Continuing Enforcement Issue: Failure to Manage Identified Risk

- The Risk Management Standard requires the "[implementation of] security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with [the Security Rule]." See 45 C.F.R. § 164.308(a)(1)(ii)(B).
- Investigations conducted by OCR regarding several instances of breaches uncovered that risks attributable to a reported breach had been previously identified as part of a risk analysis, but that the breaching organization failed to act on its risk analysis and implement appropriate security measures.
- In some instances, encryption was included as part of a remediation plan; however, activities to implement encryption were not carried out or were not implemented within a reasonable timeframe as established in a remediation plan.

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Mobile Device Security

http://www.healthit.gov/mobiledevices

Continuing Enforcement Issue: Lack of Transmission Security

- When electronically transmitting ePHI, a mechanism to encrypt the ePHI must be implemented whenever deemed appropriate. See 45 C.F.R. § 164.312(e)(2)(ii).
- Applications for which encryption should be considered when transmitting ePHI may include:
  - Email
  - Texting
  - Application sessions
  - File transmissions (e.g., ftp)
  - Remote backups
  - Remote access and support sessions (e.g., VPN)

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Continuing Enforcement Issue: Lack of Appropriate Auditing

- The HIPAA Rules require the "[implementation] of hardware, software, and/or procedural mechanisms that record and examine activity in information systems that contain or use electronic protected health information." See 45 C.F.R. § 164.312(b).
- Once audit mechanisms are put into place on appropriate information systems, procedures must be implemented to "regularly review records of information system activity, such as audit logs, access reports, and security incident tracking reports." See 45 C.F.R. § 164.308(a)(1)(ii)(D).
- Activities which could warrant additional investigation:
  - Access to PHI during non-business hours or during time off
  - Access to an abnormally high number of records containing PHI
  - Access to PHI of persons for which media interest exists
  - Access to PHI of employees

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Continuing Enforcement Issue: Patching of Software

- The use of unpatched or unsupported software on systems which access ePHI could introduce additional risk into an environment.
- Continued use of such systems must be included within an organization's risk analysis and appropriate mitigation strategies implemented to reduce risk to a reasonable and appropriate level.
- In addition to operating systems, EMR/PM systems, and office productivity software, software which should be monitored for patches and vendor end-of-life for support include:
  - Router and firewall firmware
  - Anti-virus and anti-malware software
  - Multimedia and runtime environments (e.g., Adobe Flash, Java, etc.)

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Continuing Enforcement Issue: Insider Threat

- Organizations must "[i]mplement policies and procedures to ensure that all members of its workforce have appropriate access to electronic protected health information … and to prevent those workforce members who do not have access … from obtaining access to electronic protected health information," as part of its Workforce Security plan. See 45 C.F.R. § 164.308(a)(3).
- Appropriate workforce screening procedures could be included as part of an organization's Workforce Clearance process (e.g., background and OIG LEIE checks). See 45 C.F.R. § 164.308(a)(3)(ii)(B).
- Termination Procedures should be in place to ensure that access to PHI is revoked as part of an organization's workforce exit or separation process. See 45 C.F.R. § 164.308(a)(3)(ii)(C).

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Continuing Enforcement Issue: Disposal of PHI

- When an organization disposes of electronic media which may contain ePHI, it must implement policies and procedures to ensure that proper and secure disposal processes are used. See 45 C.F.R. § 164.310(d)(2)(i).
- The implemented disposal procedures must ensure that "[e]lectronic media have been cleared, purged, or destroyed consistent with *NIST Special Publication 800–88: Guidelines for Media Sanitization*, such that the PHI cannot be retrieved."
- Electronic media and devices identified for disposal should be disposed of in a timely manner to avoid accidental improper disposal.
- Organizations must ensure that all electronic devices and media containing PHI are disposed of securely; including non-computer devices such as copier systems and medical devices.

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Continuing Enforcement Issue: Insufficient Backup and Contingency Planning

- Organizations must ensure that adequate contingency plans (including data backup and disaster recovery plans) are in place and would be effective when implemented in the event of an actual disaster or emergency situation. See 45 C.F.R. § 164.308(a)(7).
- Leveraging the resources of cloud vendors may aid an organization with its contingency planning regarding certain applications or computer systems, but may not encompass all that is required for an effective contingency plan.
- As reasonable and appropriate, organizations must periodically test their contingency plans and revise such plans as necessary when the results of the contingency exercise identify deficiencies. See 164.308(a)(7)(ii)(D).

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Questions

- http://www.hhs.gov/hipaa
- Join us on Twitter @hhsocr

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